

1377 Nottingham Road  
Charleston, WV 25314  
April 11, 1999

Dockets Management Branch (HFA-305)  
Docket No. 98N-1265  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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Dear Person,

I strongly oppose the draft memorandum of understanding being proposed by the FDA. The definition of "inordinate amount" will restrict my right to obtain medically necessary compounded medications.

I took Premarin and Provera for years, and kept having fibrocystic breast disease. Women do have intuition, and I knew on some level that these facts were connected. But I was at extreme risk for osteoporosis, and was advised by every doctor I saw to continue hormone replacement therapy. Never was there any attempt to find out what the correct dosage was for me. The dosage would have been the same if I weighed 120 pounds or 220 pounds. Of course, weight is only one of many factors that make me an individual who responds differently to medications than others.

Then the fibrocystic breast disease got worse and worse. Finally I had two surgeries within 8 months of each other to remove 3 lumps as well as a needle aspiration for another. Breast cancer runs in my family, and this was quite frightening. Even though the tissue removed was benign, it became clear that I would continue to have lumps until one of them was cancer. I began to read and read and read. What I learned has changed my life and saved it.

My gynecologist retired and I found a new one. He agreed that I should find out what my own individual dosage needs were. We used saliva testing which is a new and much more exact testing method than blood tests. These tests are a part of the individual patient plan from Madison Pharmacy of Madison, Wisconsin. Nothing like this exists in West Virginia. The test results were truly frightening. They showed that somehow I do not absorb Provera in a way that makes it available to my body. I was getting plenty of estrogen, but practically no progesterone. My doctor called it "unopposed estrogen" and says it is a recipe for causing cancer.

Thanks to Madison Pharmacy's long experience in this field, they were able to recommend specifically compounded hormones for me. My doctor read the recommendations and agreed with them. I started these hormones in July of 1998. In September, more tests were done. At that time, the level of available progesterone was higher, but not high enough. Dosages were adjusted. Today, I have taken the tests again. Soon, my doctor and I will know if we have finally found the correct dosages for me. If not, we can adjust and try again. But not, if you restrict the interstate sale of medications.

I feel so much better on these medications. The constant soreness of my breasts is gone. I have more energy. I do have osteoporosis now, however, and need hormones to keep it at bay. But I will not go back to Premarin, Provera, or anything other than pure hormones. Drug companies do not make pure hormones because they cannot be patented. Even if I can find a compounding pharmacy in West Virginia, it will not have the years of experience and the expertise to help me like Madison Pharmacy can and does.

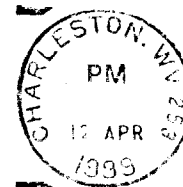
Thank you for your consideration of this letter.

98N-1265

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Jeanette Beisner

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